

and dated Copy 2 or the written report (see § 40.163(b) and (c)).

(2) Negative results reported electronically (i.e., computer data file) do not require an image of Copy 2 or the written report.

(d) In transmitting test results, you or the C/TPA and the employer must ensure the security of the transmission and limit access to any transmission, storage, or retrieval systems.

(e) MRO reports are not subject to modification or change by anyone other than the MRO, as provided in § 40.149(c).

[65 FR 79526, Dec. 19, 2000, as amended at 66 FR 41953, Aug. 9, 2001]

§ 40.169 Where is other information concerning the role of MROs and the verification process found in this regulation?

You can find more information concerning the role of MROs in several sections of this part:

§ 40.3—Definition.

§§ 40.47–40.49—Correction of form and kit errors.

§ 40.67—Role in direct observation and other atypical test situations.

§ 40.83—Laboratory handling of fatal and correctable flaws.

§ 40.97—Laboratory handling of test results and quantitative values.

§ 40.99—Authorization of longer laboratory retention of specimens.

§ 40.101—Relationship with laboratories; avoidance of conflicts of interest.

§ 40.105—Notification of discrepancies in blind specimen results.

§ 40.171—Request for test of split specimen.

§ 40.187—Action concerning split specimen test results.

§ 40.193—Role in “shy bladder” situations.

§ 40.195—Role in cancelling tests.

§§ 40.199–40.203—Documenting errors in tests.

§ 40.327—Confidentiality and release of information.

§ 40.347—Transfer of records.

§ 40.353—Relationships with service agents.

Subpart H—Split Specimen Tests

§ 40.171 How does an employee request a test of a split specimen?

(a) As an employee, when the MRO has notified you that you have a verified positive drug test and/or refusal to test because of adulteration or substitution, you have 72 hours from the time of notification to request a

test of the split specimen. The request may be verbal or in writing. If you make this request to the MRO within 72 hours, you trigger the requirements of this section for a test of the split specimen. There is no split specimen testing for an invalid result.

(b)(1) If, as an employee, you have not requested a test of the split specimen within 72 hours, you may present to the MRO information documenting that serious injury, illness, lack of actual notice of the verified test result, inability to contact the MRO (*e.g.*, there was no one in the MRO’s office and the answering machine was not working), or other circumstances unavoidably prevented you from making a timely request.

(2) As the MRO, if you conclude from the employee’s information that there was a legitimate reason for the employee’s failure to contact you within 72 hours, you must direct that the test of the split specimen take place, just as you would when there is a timely request.

(c) When the employee makes a timely request for a test of the split specimen under paragraphs (a) and (b) of this section, you must, as the MRO, immediately provide written notice to the laboratory that tested the primary specimen, directing the laboratory to forward the split specimen to a second HHS-certified laboratory. You must also document the date and time of the employee’s request.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008]

§ 40.173 Who is responsible for paying for the test of a split specimen?

(a) As the employer, you are responsible for making sure (*e.g.*, by establishing appropriate accounts with laboratories for testing split specimens) that the MRO, first laboratory, and second laboratory perform the functions noted in §§ 40.175–40.185 in a timely manner, once the employee has made a timely request for a test of the split specimen.

(b) As the employer, you must not condition your compliance with these requirements on the employee’s direct payment to the MRO or laboratory or the employee’s agreement to reimburse

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you for the costs of testing. For example, if you ask the employee to pay for some or all of the cost of testing the split specimen, and the employee is unwilling or unable to do so, you must ensure that the test takes place in a timely manner, even though this means that you pay for it.

(c) As the employer, you may seek payment or reimbursement of all or part of the cost of the split specimen from the employee (*e.g.*, through your written company policy or a collective bargaining agreement). This part takes no position on who ultimately pays the cost of the test, so long as the employer ensures that the testing is conducted as required and the results released appropriately.

§ 40.175 What steps does the first laboratory take with a split specimen?

(a) As the laboratory at which the primary and split specimen first arrive, you must check to see whether the split specimen is available for testing.

(b) If the split specimen is unavailable or appears insufficient, you must then do the following:

(1) Continue the testing process for the primary specimen as you would normally. Report the results for the primary specimen without providing the MRO information regarding the unavailable split specimen.

(2) Upon receiving a letter from the MRO instructing you to forward the split specimen to another laboratory for testing, report to the MRO that the split specimen is unavailable for testing. Provide as much information as you can about the cause of the unavailability.

(c) As the laboratory that tested the primary specimen, you are not authorized to open the split specimen under any circumstances (except when the split specimen is redesignated as provided in § 40.83).

(d) When you receive written notice from the MRO instructing you to send the split specimen to another HHS-certified laboratory, you must forward the following items to the second laboratory:

(1) The split specimen in its original specimen bottle, with the seal intact;

(2) A copy of the MRO's written request; and

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(3) A copy of Copy 1 of the CCF, which identifies the drug(s)/metabolite(s) or the validity criteria to be tested for.

(e) You must not send to the second laboratory any information about the identity of the employee. Inadvertent disclosure does not, however, cause a fatal flaw.

(f) This subpart does not prescribe who gets to decide which HHS-certified laboratory is used to test the split specimen. That decision is left to the parties involved.

§ 40.177 What does the second laboratory do with the split specimen when it is tested to reconfirm the presence of a drug or drug metabolite?

(a) As the laboratory testing the split specimen, you must test the split specimen for the drug(s)/drug metabolite(s) detected in the primary specimen.

(b) You must conduct this test without regard to the cutoff concentrations of § 40.87.

(c) If the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) that were reported positive in the primary specimen, you must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug(s)/metabolite(s). You should conduct the same validity tests as you would conduct on a primary specimen set forth in § 40.91.

(d) In addition, if the test fails to reconfirm the presence of the drug(s)/drug metabolite(s) reported in the primary specimen, you may send the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008]

§ 40.179 What does the second laboratory do with the split specimen when it is tested to reconfirm an adulterated test result?

(a) As the laboratory testing the split specimen, you must test the split specimen for the adulterant detected in the primary specimen, using the confirmatory test for the adulterant and using

criteria in § 40.95 and confirmatory cut-off levels required by the HHS Mandatory Guidelines.

(b) In addition, if the test fails to reconfirm the adulterant result reported in the primary specimen, you may send the specimen or an aliquot of it for testing at another HHS-certified laboratory that has the capability to conduct another reconfirmation test.

[73 FR 35973, June 25, 2008]

§ 40.181 What does the second laboratory do with the split specimen when it is tested to reconfirm a substituted test result?

As the laboratory testing the split specimen, you must test the split specimen using the confirmatory tests for creatinine and specific gravity, and using the confirmatory criteria set forth in § 40.93(b).

[73 FR 35973, June 25, 2008]

§ 40.183 What information do laboratories report to MROs regarding split specimen results?

(a) As the laboratory responsible for testing the split specimen, you must report split specimen test results by checking the "Reconfirmed" box and/or the "Failed to Reconfirm" box (Step 5(b)) on Copy 1 of the CCF, as appropriate, and by providing clarifying remarks using current HHS Mandatory Guidelines requirements.

(b) As the laboratory certifying scientist, enter your name, sign, and date the CCF.

[65 FR 79526, Dec. 19, 2000, as amended at 73 FR 35972, June 25, 2008]

§ 40.185 Through what methods and to whom must a laboratory report split specimen results?

(a) As the laboratory testing the split specimen, you must report laboratory results directly, and only, to the MRO at his or her place of business. You must not report results to or through the DER or another service agent (*e.g.*, a C/TPA).

(b) You must fax, courier, mail, or electronically transmit a legible image or copy of the fully-completed Copy 1 of the CCF, which has been signed by the certifying scientist.

(c) You must transmit the laboratory result to the MRO immediately, preferably on the same day or next business day as the result is signed and released.

§ 40.187 What does the MRO do with split specimen laboratory results?

As the MRO, the split specimen laboratory results you receive will fall into five categories. You must take the following action, as appropriate, when a laboratory reports split specimen results to you.

(a) *Category 1:* The laboratory reconfirmed one or more of the primary specimen results. As the MRO, you must report to the DER and the employee the result(s) that was/were reconfirmed.

(1) In the case of a reconfirmed positive test(s) for drug(s) or drug metabolite(s), the positive is the final result.

(2) In the case of a reconfirmed adulterated or substituted result, the refusal to test is the final result.

(3) In the case of a combination positive and refusal to test results, the final result is both positive and refusal to test.

(b) *Category 2:* The laboratory failed to reconfirm all of the primary specimen results because, as appropriate, drug(s)/drug metabolite(s) were not detected; adulteration criteria were not met; and/or substitution criteria were not met. As the MRO, you must report to the DER and the employee that the test must be cancelled.

(1) As the MRO, you must inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In a case where the split failed to reconfirm because the substitution criteria were not met and the split specimen creatinine concentration was equal to or greater than 2mg/dL but less than or equal to 5mg/dL, as the MRO, you must, in addition to step (b)(1) of this paragraph, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(3) In a case where the split failed to reconfirm and the primary specimen's

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result was also invalid, direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(c) *Category 3:* The laboratory failed to reconfirm all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted.

(1) In the case where the laboratory failed to reconfirm all of the primary specimen results and the split was reported as invalid, as the MRO, you must:

(i) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation.

(ii) Direct the DER to ensure the immediate collection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection.

(iii) Inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(2) In the case where the laboratory failed to reconfirm any of the primary specimen results, and the split was reported as adulterated and/or substituted, as the MRO, you must:

(i) Contact the employee and inform the employee that the laboratory has determined that his or her split specimen is adulterated and/or substituted, as appropriate.

(ii) Follow the procedures of §40.145 to determine if there is a legitimate medical explanation for the laboratory finding of adulteration and/or substitution, as appropriate.

(iii) If you determine that there is a legitimate medical explanation for the adulterated and/or substituted test result, report to the DER and the employee that the test must be cancelled; and inform ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(iv) If you determine that there is not a legitimate medical explanation for the adulterated and/or substituted test result, you must take the following steps:

(A) Report the test to the DER and the employee as a verified refusal to test. Inform the employee that he or she has 72 hours to request a test of the primary specimen to determine if the adulterant found in the split specimen is also present in the primary specimen and/or to determine if the primary specimen meets appropriate substitution criteria.

(B) Except when the request is for a test of the primary specimen and is being made to the laboratory that tested the primary specimen, follow the procedures of §§40.153, 40.171, 40.173, 40.179, 40.181, and 40.185, as appropriate.

(C) As the laboratory that tests the primary specimen to reconfirm the presence of the adulterant found in the split specimen and/or to determine that the primary specimen meets appropriate substitution criteria, report your result to the MRO on a photocopy (faxed, mailed, scanned, couriered) of Copy 1 of the CCF.

(D) If the test of the primary specimen reconfirms the adulteration and/or substitution finding of the split specimen, as the MRO you must report the result as a refusal to test as provided in paragraph (a)(2) of this section.

(E) If the test of the primary specimen fails to reconfirm the adulteration and/or substitution finding of the split specimen, as the MRO you must cancel the test, following procedures in paragraph (b) of this section.

(d) *Category 4:* The laboratory failed to reconfirm one or more but not all of the primary specimen results, and also reported that the split specimen was invalid, adulterated, and/or substituted. As the MRO, in the case where the laboratory reconfirmed one or more of the primary specimen result(s), you must follow procedures in paragraph (a) of this section and:

(1) Report that the split was also reported as being invalid, adulterated, and/or substituted (as appropriate).

(2) Inform the DER to take action only on the reconfirmed result(s).

(e) *Category 5:* The split specimen was not available for testing or there was no split laboratory available to test the specimen. As the MRO, you must:

(1) Report to the DER and the employee that the test must be cancelled and the reason for the cancellation;

(2) Direct the DER to ensure the immediate recollection of another specimen from the employee under direct observation, with no notice given to the employee of this collection requirement until immediately before the collection; and

(3) Notify ODAPC of the failure to reconfirm using the format in Appendix D to this part.

(f) For all split specimen results, as the MRO you must:

(1) Enter your name, sign, and date (Step 7) of Copy 2 of the CCF.

(2) Send a legible copy of Copy 2 of the CCF (or a signed and dated letter, see § 40.163) to the employer and keep a copy for your records. Transmit the document as provided in § 40.167.

[73 FR 35973, June 25, 2008]

§ 40.189 Where is other information concerning split specimens found in this regulation?

You can find more information concerning split specimens in several sections of this part:

§ 40.3—Definition.

§ 40.65—Quantity of split specimen.

§ 40.67—Directly observed test when split specimen is unavailable.

§§ 40.71–40.73—Collection process for split specimens.

§ 40.83—Laboratory accessioning of split specimens.

§ 40.99—Laboratory retention of split specimens.

§ 40.103—Blind split specimens.

§ 40.153—MRO notice to employees on tests of split specimen.

§§ 40.193 and 40.201—MRO actions on insufficient or unavailable split specimens.

APPENDIX D TO PART 40—REPORT FORMAT FOR SPLIT SPECIMEN FAILURE TO RECONFIRM.

Subpart I—Problems in Drug Tests

§ 40.191 What is a refusal to take a DOT drug test, and what are the consequences?

(a) As an employee, you have refused to take a drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the employer, consistent with applicable DOT agency regulations, after being directed to do so by the employer. This includes the failure of an employee (including an owner-operator) to appear

for a test when called by a C/TPA (see § 40.61(a));

(2) *Fail to remain at the testing site until the testing process is complete; Provided, That an employee who leaves the testing site before the testing process commences (see § 40.63 (c)) for a pre-employment test is not deemed to have refused to test;*

(3) Fail to provide a urine specimen for any drug test required by this part or DOT agency regulations; *Provided, That an employee who does not provide a urine specimen because he or she has left the testing site before the testing process commences (see § 40.63 (c)) for a pre-employment test is not deemed to have refused to test;*

(4) In the case of a directly observed or monitored collection in a drug test, fail to permit the observation or monitoring of your provision of a specimen (see §§ 40.67(1) and 40.69(g));

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure (see § 40.193(d)(2));

(6) Fail or decline to take an additional drug test the employer or collector has directed you to take (see, for instance, § 40.197(b));

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process, or as directed by the DER under § 40.193(d). In the case of a pre-employment drug test, the employee is deemed to have refused to test on this basis only if the pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test; or

(8) Fail to cooperate with any part of the testing process (e.g., refuse to empty pockets when directed by the collector, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector).

(9) For an observed collection, fail to follow the observer's instructions to raise your clothing above the waist, lower clothing and underpants, and to turn around to permit the observer to determine if you have any type of prosthetic or other device that could be